



CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant or Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Michelle L. McKinley
Regulatory Specialist

Proprietary Name: M2a™ Acetabular System

Common or Usual Name: acetabular cup prosthesis

Classification Name: prosthesis, hip, semi-constrained, metal/polymer, uncemented
(888.3330)

Device Product Code: 87 KWA

Substantially Equivalent Devices: M2a™ Acetabular System, McKee Farrar, DePuy
Pinnacle Metal-on-Metal Acetabular Cup Liners

Device Description:

Acetabular Shell

The 38mm M2a™ acetabular cup is cobalt chromium one-piece cup. The hemispherical shape of the acetabular cup closely matches the natural acetabulum, which leads to minimal bone removal in preparation for implantation. The inner surface of the cup is the bearing surface.

Modular Femoral Head

The 38mm M2a™ acetabular cup utilizes a 38mm cobalt-chromium (Co-Cr-Mo) modular femoral head. The modular heads may be used in conjunction with any of Biomet's commercially available Type I taper femoral components.

Intended Use:

The M2a™ Acetabular System is indicated for use in patients requiring total hip replacement due to the following:

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

000106

BIOMET

CORPORATE HEADQUARTERS

- a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis
- b.) Rheumatoid arthritis
- c.) Correction of functional deformity
- d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
- e.) Revision of previously failed total hip arthroplasty.

Basis of Substantial Equivalence:

In terms of overall design and intended use, the M2a™ Acetabular System is equivalent to all other total hip acetabular components. Specifically, the geometry, materials, and fixation enhancements are similar to the following devices:

- 1. M2a™ Acetabular System: K993438, K003363
- 2. McKee Farrar: Pre-amendment Device
- 3. DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners: K003523

Mechanical testing was also used to determine substantial equivalence.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

000107